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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,710	09/29/2003	Robert G. Turcott	A03P3004-US1.	4592

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EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,710	TURCOTT, ROBERT G.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *24-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1–23 in the reply filed on 04 May 2006 is acknowledged.

Response to Arguments

2. Applicant's arguments filed on 04 May 2006 have been fully considered but they are not persuasive. On page 13 of Applicant's REMARKS, it is not apparent why Applicant states the Bornzin et al. references in lines 6–23 with portions of the statements emphasized with underlining. Applicant has not specifically indicated how these references relate to the claim limitations of claim 1 as recited in the present application. Examiner respectfully disagrees with Applicant's argument that Bornzin et al. do not disclose or suggest estimating optimal control parameters for maximizing cardiac performance based on the values representative of transient cardiac performance as recited in claim 1 of the present application. Bornzin et al. disclose the claimed limitation at column 5, lines 5–12 and column 19, line 36–column 21, line 30 as stated in the Office Action mailed on 07 February 2006. Specifically, the estimating step is shown as averaged/average functions of the processor, 28 in column 20 lines, 53–65 and column 21, lines 4–30 where the estimated (averaged) optimal control parameters are HR_{OPT}, AV_{OPT} and P_{OPT} as described in the function of the processor, 28. Further, the processor provides the information it gathers from the values representative of transient cardiac performance (AV, HR) to maximize cardiac performance as described in the cited Bornzin et al. references herein above, and as recited in claim 1 of the present application.

3. Consequently, Examiner maintains the 35 U.S.C. § 102(b) rejection for claims 1–2, 4–7, 9, 12–21, and 23 as being anticipated by Bornzin et al., U.S. Patent 5,549,6501 and the 35 U.S.C. § 103(a) rejections for claims 3, 8, and 22 as being dependent from the rejected parent claim 1 and as set forth in the aforementioned Office Action and as resubmitted in its entirety herein below.

4. As a matter of correction, Examiner brings to Applicant's attention that claim 17 has not been provided with the proper status identifier, and as such, the individual status of the claim cannot be identified. The status of every amended claim must be indicated after its claim number. In this case, the claim identifier for claim 17 should read (Currently Amended) rather than (Original) as it is currently identified in the amended claims that were submitted on 04 May 2006.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1–2, 4–7, 9, 12–21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bornzin et al., U.S. Patent 5,549,650.

7. Bornzin discloses controlling an implantable device to deliver therapy to the heart of a patient while switching among sets of control parameters during a series of consecutive evaluation periods that are substantially equal in duration to one another (Figs. 9–11; column 18, lines 20–24); detecting values representative of transient cardiac performance corresponding to

the different sets of control parameters, and estimating optimal control parameters for maximizing cardiac performance based on the values representative of transient cardiac performance (claim 1) (Figs. 10–11; column 5, lines 5–12; column 19, line 36–column 21, line 30); evaluation periods are sufficiently short so that hemodynamic feedback systems of a patient do not have time to readjust the cardiovascular system of the patient to a substantially equilibrium state before the control parameters are switched again (claim 2) (column 9, lines 21 – 33); evaluation periods are no longer two respiratory cycles each (claim 4) and periods of time over which the values representative of transient cardiac performance are measured are each set equal to substantially identical portions of a respiratory cycle, wherein each respiratory cycle comprises one inspiration and one expiration (claim 7) (Fig. 11); the step of detecting values representative of transient cardiac performance is performed to detect changes in transient cardiac performance from one consecutive evaluation period to another (claim 5) (column 20, lines 3–25); and wherein the step of estimating an optimal set of control parameters is performed based on the changes in transient cardiac performance (claim 5) (Fig. 4; column 19, lines 15–18); the step of detecting changes in transient cardiac performance comprises the steps of: measuring values representative of transient cardiac performance of the heart of the patient during each evaluation period, and determining the difference in transient cardiac performance based on a comparison of the measured values (claim 6) (column 20, lines 35–47); the step of controlling the implantable device to deliver therapy to the heart of the patient while switching among sets of control parameters comprises controlling an implantable device to deliver therapy to the heart of the patient by alternating, from one evaluation period to another, between different sets of selected test control parameters and a set of reference control parameters (claim 9) (column 21,

lines 4–30), cycling through different sets of selected test control parameters to provide for all possible changes between sets of control parameters (claim 12) (column 20, lines 26–34), and cycling through different sets of selected test control parameters to provide for only a sub-set of all possible changes between sets of control parameters (claim 13) (column 20, lines 3–25); the step of determining the difference in transient cardiac performance based on a comparison of the measured values includes the steps of: detecting a value representative of transient cardiac performance during an immediately preceding evaluation period, detecting a value representative of transient cardiac performance during the given evaluation period, and generating a difference value representative of a change in transient cardiac performance between the prior evaluation period and the given evaluation period such that a single difference value is generated for each evaluation period (claim 14) (column 21, lines 4–30); the step of estimating an optimal set of control parameters includes the steps of: associating each difference value with a set of control parameters employed during a corresponding evaluation period, fitting a single/separate curve to the difference values versus associated test parameter values/a set of parameter values; and identifying a set of preferred control parameters providing maximal difference values as indicated by a single/separate curve and averaging a separate sets of preferred control parameters together to yield a single set of control parameters (claims 15–16) (Figs. 10–11; column 21, lines 4–30); the step of controlling an implantable device to deliver therapy while switching control parameters is performed to adaptively adjust control parameters based on resulting changes in cardiac performance (claim 17) (column 20, lines 35–47); and wherein the step of estimating optimal control parameters for maximizing cardiac performance comprises identifying control parameters that result in the most positive difference in cardiac performance as compared to all

other control parameter values (claim 17) (column 20, lines 35–44); control parameters include one or more of: pacing base rate; maximum tracking rate; minimum tracking rate, atrioventricular (AV) delay and interventricular delay (claim 18) (Fig. 11); the step of detecting values representative of transient cardiac performance is performed to detect values representative of one or more of stroke volume, cardiac output, end-diastolic volume, end-systolic volume, ejection fraction, cardiac output index, flow through the mitral valve, maximum rate of change of left ventricular pressure with time, maximum rate of change of aortic pressure with time, mean arterial pressure, arterial pulse pressure, vascular volume, and vascular photoplethysmography (claim 19) (column 19, lines 9–12); the initial step of determining whether to initiate an optimization procedure based on a change in one or more of patient posture, heart rate, activity levels, autonomic tone, and fluid status (claim 20) (Figs. 1, 5–10; column 7, lines 60–62; column 15, lines 18–26); the steps of the method are performed periodically (claim 21) (Figs. 9–10); all steps of the method are performed by the implantable device(claim 23) (Fig. 10; column 21, lines 36–42).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 3 and 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin et al., U.S. Patent 5,549,650.

10. Bornzin discloses the claimed invention except for the evaluation periods are not longer than 12 seconds each (claim 3) and each set equal to about four seconds (claim 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include evaluation periods are not longer than 12 seconds each and each set equal to about four seconds, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). (See MPEP 2144.05).

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin et al. as and in view of Baumann, U.S. Patent 5,800,471.

12. Bornzin does not disclose the step of controlling an implantable device to deliver therapy to the heart of a patient while changing control parameters is performed by an external programmer device. However, Baumann discloses the step of controlling an implantable device to deliver therapy to the heart of a patient while changing control parameters is performed by an external programmer device (column 5, lines column 9, lines 24–30) to arrive at the optimal pacing mode-AV delay interval (column 9, lines 29–30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of Bornzin to include the step of controlling an implantable device to deliver therapy to the heart of a patient while changing control parameters is performed by an external programmer device, as taught by Baumann to optimize the performance of the implantable device.

Allowable Subject Matter

13. Claims 10–11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
October 2, 2006
20 October 2006

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